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Regulatory Proposal

PRO2010-05

# Revised Management of Submissions Policy

*(publié aussi en français)*

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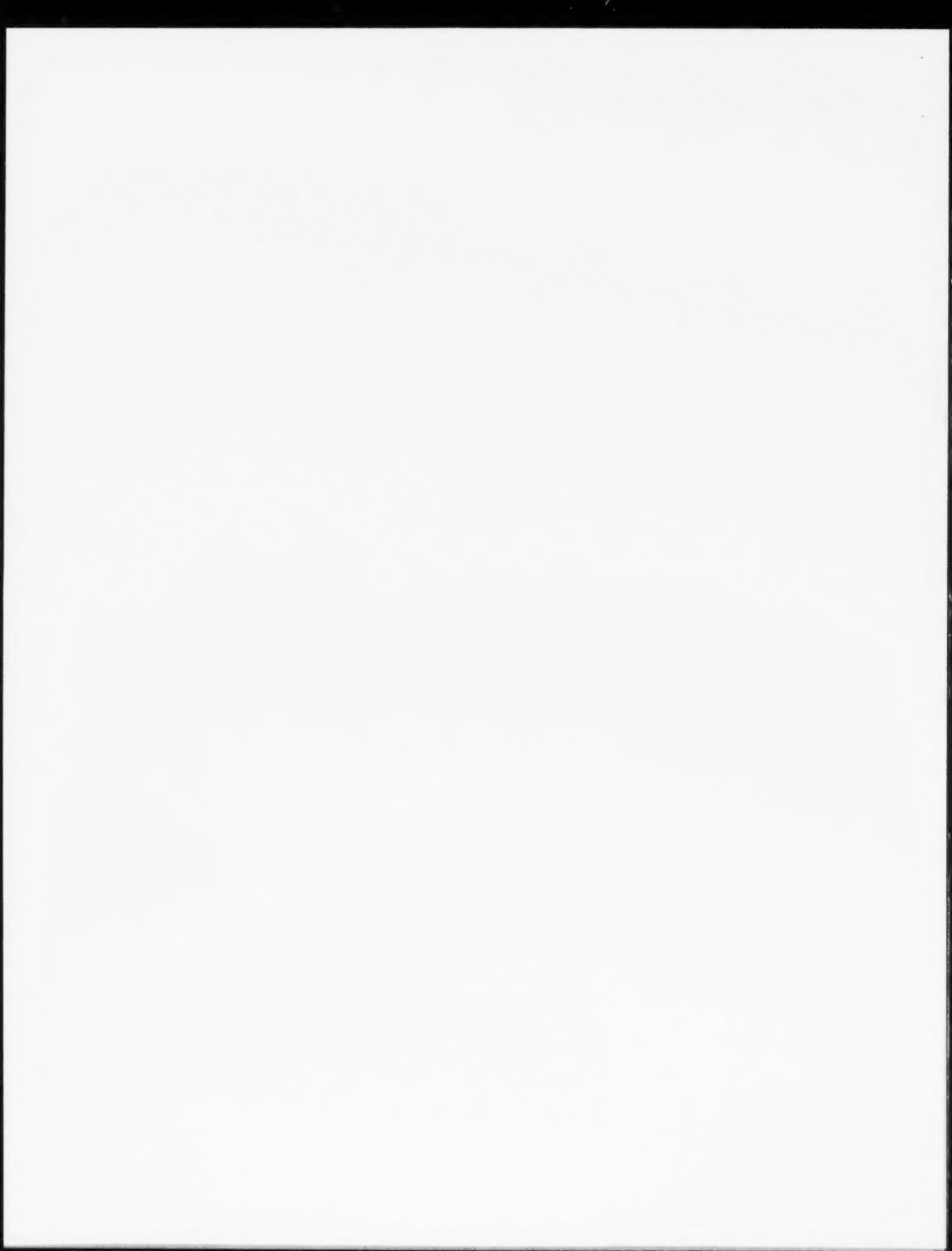
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## 1.0 Purpose

Pursuant to the *Pest Control Products Act*, no person can manufacture, possess, handle, store, transport, import, distribute or use a pest control product that is not registered under the *Pest Control Products Act*, except as otherwise authorized under the Act or unless specifically exempted by the Pest Control Products Regulations.

The purpose of this consultation document is two-fold:

- To consult with industry and other interested parties regarding proposed revisions to submission management processes documented in Regulatory Proposal PRO96-01, *Management of Submissions Policy*, and regarding proposed changes to the measurement of performance for applications subject to the Management of Submissions Policy (MOSP).
- To consolidate into one place all the current performance timelines and standards for managing applications submitted to Health Canada's Pest Management Regulatory Agency (PMRA).

The proposed amendments will result in a submission management process which is more efficient, effective, and predictable for applicants/registrants and the PMRA. The expected result will be a closer alignment of the management of submissions with approaches used by regulatory authorities in other jurisdictions. This, in the future, will facilitate work-share and joint review of applications with other jurisdictions.

## 2.0 Scope

This document pertains to all applications for:

- the registration or amendment of a pest control product
- the specification of a maximum residue limit (MRL)
- the authorization or notification of research
- the issuance of an equivalency certificate and authorization of importation for own use
- the conduct of presubmission consultations and examination of submissions under the User Requested Minor Use Label Expansion (URMULE) Programme.

The same general process applies to all categories of submissions. However, some steps are not required for all categories. Depending on the purpose of the application and the type of information required, every submission subject to the MOSP is assigned to one of the five following categories:

#### **Category A**

- New active ingredients or integrated system products, their related end-use products, and manufacturing-use products
- Major new use of registered pest control products (defined as the addition of a new use-site category to the use pattern for a specific registered active ingredient)
- Specification of import MRLs for a new active ingredient

#### **Category B**

- New pest control products containing registered active ingredients
- Amendment to existing pest control products (for example, product chemistry, labelling)
- Conversion or renewal of conditional registration
- Emergency registration
- The addition of import MRLs for previously assessed active ingredients

#### **Category C**

- Product registrations and amendments with no data requirements. These applications involve minor label or formulation reviews, such as product registration based on registered precedent products. (Note: It is proposed that "streamlined Category Cs", which do require the review of data, be reclassified as "streamlined Category Bs" while keeping the same review timeline)

#### **Category D**

- Submissions within particular programs including:
  - Import for Manufacture and Export Program (IMEP)
  - Own Use Import (OUI)
  - Grower Requested Own Use (GROU) Equivalency and import permits
  - Master Copy
  - Private Label
  - User Requested Minor Use Label Expansion (URMULE)
  - Registration Renewal
  - Discontinuations

#### **Category E**

- Research authorizations for new active ingredients and new use(s) of registered active ingredients
- Research notification for research carried out in Canada.

The current MOSP performance timelines for each submission category are consolidated in Appendix I, Tables 1 to 5 (for Categories A to E respectively). Note: Within each category there are further subdivisions (for example, submission subcategories, submission types, classes) that may have shorter performance timelines because they follow reduced-risk<sup>1</sup> timelines and/or have fewer data requirements and/or are conducted under specific programs (for example, Joint Review, URMUR, Program 914).

### **3.0 Instructions for Submitting an Application**

Various guidance documents are available on the Pesticides and Pest Management portion of Health Canada's website to help applicants prepare a complete application package. Instructions on applying for registration can be found in Regulatory Directive DIR2006-05, *Requirements for Submitting Data Index, Documents and Forms*.

### **4.0 Proposed Revisions to the Management of Submissions Policy Process**

The following sections provide a step-by-step (level-by-level) description of the submission review process according to the MOSP, with proposed changes to the MOSP being highlighted for each step. (Note: The proposed amendments are not intended to change the current submission classification or the timeline of each category. However, it is expected that changes in submissions management will make the overall process more efficient).

Under the MOSP, applications are typically reviewed in chronological order within each MOSP category subdivision. However, under certain circumstances, an expedited review may be considered if there is a critical need, for example, to replace an active ingredient being phased out through re-evaluation, a formulation amendment to replace a formulant of concern, products needed to mitigate a public health or environmental risk, or to resolve repeated requirements for emergency registrations. In addition, related submissions may be grouped so that they follow the same review timeline.

Proposed revisions to the MOSP performance timelines in calendar days are summarized in Appendix II, Tables 1 to 5 (for Categories A to E respectively).

A submission flow diagram is depicted in Appendix III to illustrate the proposed revisions to the MOSP submission examination process for a standard Category A submission. Other categories will follow the same process using the performance timelines provided in Appendix II. However, some steps will not apply to every submission category subdivision (for example, public consultation is not required for Category C submissions).

To summarize the proposed changes, a high-level comparison of the current MOSP versus the proposed changes in the revised MOSP is provided in Appendix IV.

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<sup>1</sup> Reduced risk refers to the expedited review timelines as outlined in Regulatory Directive DIR2002-02: *The PMRA Initiative for Reduced-Risk Pesticides*.

#### **4.1 Completeness Check (Verification and Screening).**

A completeness check will be performed on all submissions to ensure a complete submission has been received before the review stage is started. The proposed performance timelines for the completeness check are outlined in Appendix II. When the submission is received by the PMRA, the completeness check clock will start. The completeness check will generally consist of an initial verification step and a more detailed screening step.

The proposed change in the revised MOSP is the combining and shortening of the verification and screening timelines. For most submission types, this is reduced to a 37 day timeline versus the current approach where there is seven days for verification and 45 days for screening.

##### **4.1.1 Verification**

For most submission categories/subtypes there is a seven calendar day verification step during which submissions are verified to ensure that non-data elements including the covering letter, the appropriate application form, the Statement of Product Specification Form, the fee form, the fee and the e-index have been provided. A submission found to be deficient at the verification step will result in an e-mail, outlining the deficiencies, being sent to the applicant and the submission being placed "on-hold". The applicant is given 14 calendar days to address the deficiencies. When a response is received from the applicant, a second verification period of a maximum of seven calendar days will apply and the completeness check clock will be reset to day 0. Lack of an adequate response will result in the submission being rejected.

Applicants are provided a submission number acknowledging receipt of the submission. This number should appear on all subsequent correspondence to the Agency relating to that submission.

The proposed change in the revised MOSP is to allow applicants 14 days to respond to the "on-hold" e-mail during the verification stage. (Note: the practise of "on-hold" at verification has been in place for several years.)

##### **4.1.2 Screening**

For most submission categories/subtypes there is a 30 calendar day screening step during which submissions are screened to ensure they meet the format, data and fee requirements of the PMRA before they are accepted for review.

##### **Clarifications**

Screening officers may request minor clarifications concerning submitted information by e-mail or facsimile (for example, clarification of the Statement of Product Specification Form). The applicant has 10 calendar days to respond to the clarification request; screening continues during this time. If an adequate response to the request for clarification is not provided within the timeframe specified, a Notice of Deficiencies will be issued. A Notice of Deficiencies can also be sent to the applicant when significant deficiencies are identified during screening.

Note: Clarifications may also be sent out during the review stage—refer to Section 4.2.

### **Notice of Deficiencies**

During the screening stage, the PMRA will place a submission "on-hold" if deficiencies are identified in the application requirements or if insufficient information has been submitted (for example, if required test data is missing). Note: deficiencies may also be identified during the review stage—refer to Section 4.2.

When a submission is placed "on-hold", the PMRA will issue a Notice of Deficiencies to the applicant to inform them of the reason for the "on-hold". The applicant must respond to the Notice of Deficiencies within the timeframe specified in the notice and supply all of the requested information as directed.

No reminders will be issued. If there is no response or if the response is incomplete or inadequate, the application will be denied in accordance with subsection 7(5) of the *Pest Control Products Act*, unless the applicant withdraws the application. The submission number will no longer be valid. Any submission that has been previously withdrawn by the applicant, or returned by the PMRA to the applicant during a previous examination, can be re-submitted at a future date. It will be considered a new submission and assigned a new submission number.

When a Notice of Deficiencies is issued at screening (at which time the completeness check clock stops), the applicant is given 45 calendar days to address the deficiencies. (Note: When one submission in a group of related submissions is put "on-hold", all of the related submissions will also be put "on-hold"). When a response to the Notice of Deficiencies is received by the PMRA, the completeness check clock will be reset with 15 calendar days on the clock. Lack of an adequate response within the specified 45 calendar day timeline will, as referred to above, result in the application being denied in accordance with subsection 7(5) of the *Pest Control Products Act*, unless the applicant withdraws the application.

The proposed changes in the revised MOSP are as follows:

- 1) A reduction in the number of days to 15 from 45 that the PMRA has to finish screening a submission after a response to the Notice of Deficiencies has been received
- 2) The screening time be shortened to 30 days from 45 days for most submission categories/subtypes
- 3) The 15 days be reallocated to the review stage

### **4.2 Review Stage**

The review stage includes the following activities:

- science evaluation of the health and environmental risks and the value of the pest control product to determine if they are acceptable
- the review of the English and French product labels
- the decision-making process

The proposed review times outlined in Appendix II are the times in calendar days that the PMRA has to conduct all of the steps in the review stage. Note: If related submissions have different review timelines, the longer review timeline will usually apply to all of the submissions in the group.

The review stage clock will start as soon as the completeness check stage is completed. Excluded from the review times is the 45 calendar day public consultation period for major regulatory decisions (for example, new active ingredients and major new uses) and for conversion/renewal of conditional registrations, both conducted via the publication of a Proposed Registration Decision.

The proposed changes in the revised MOSP are as follows:

- 1) Expanding the definition of "review" to include everything after the completeness check except the 45-day consultation period.
- 2) Removal of deficiency loops and replacing them with a start-stop review clock approach. This is expected to reduce the total time from application to decision, for applications with deficiencies, and allow the PMRA to more efficiently manage Notice of Deficiencies issued during the science evaluation stage.

#### **4.2.1 Science Evaluation**

Science evaluators may request clarifications of minor points on submitted data by e-mail or facsimile. The applicant has 10 calendar days to respond to the clarification request; the review continues during this time. If an adequate response to the request for clarification is not provided within the 10 calendar days, a Notice of Deficiencies will be issued, the submission will be placed "on-hold", and the review stage clock will stop. Note: As noted previously, when one submission in a group of related submissions is put "on-hold", all related submissions will also be put "on-hold".

If deficiencies are identified by a single science review stream at any time during the review stage, a Notice of Deficiencies will be sent to the applicant, the submission will be placed "on-hold", and the review stage clock will stop. The science review stream to which the deficiencies apply will stop that portion of the review; however, the remaining science review streams will continue to actively work on the submission during this time if this is possible and determined to be efficient. The applicant is given a specified number of days (usually 90 calendar days) to fulfil the requirements outlined in the Notice of Deficiencies. There will be no reminders provided during the "on-hold" period. When the response is received within the required timeframe, the review stage clock will restart and the affected science review stream will immediately pick up their review. Lack of a response within the required time frame will result in the application being denied in accordance with subsection 7(5) of the *Pest Control Products Act*, unless the applicant withdraws the submission.

In the event that deficiencies are identified by a second science review stream during the course of the first "on-hold", a second Notice of Deficiencies will be sent to the applicant and the review stage clock will remain stopped. The applicant will be given a specified number of days (usually 90 calendar days) from the time of the second Notice of Deficiencies to fulfil the identified data requirements. This new timeline will serve as the timeline for receipt of all data. Upon receipt of a response to a Notice of Deficiencies the science review stream for whom the deficiencies have been addressed will resume review of the submission; however, the review stage clock will remain "on-hold" if any Notices of Deficiencies remain outstanding and the review will remain stopped for any science review stream for whom a Notice of Deficiencies remains outstanding. The review stage clock will not resume until such time that a response to all outstanding Notices of Deficiencies has been received. The PMRA will issue one consolidated Notice of Deficiencies to the extent possible.

The proposed changes in the revised MOSP are as follows:

- 1) The stopping of the review stage clock, which would restart when a response is received. This approach is different from the current approach where the submission would go back to the start of the review stage.
- 2) The issuance of Notices of Deficiencies for individual review streams (for example, chemistry), to be issued as deficiencies are identified, rather than waiting to issue a consolidated Notice of Deficiencies (all review streams). The issuance of Notices of Deficiencies for individual review streams will allow the PMRA to more efficiently manage deficiencies, and is expected to reduce the total time from application to decision for those submissions that have deficiencies.

#### **4.2.2 Label Review**

The label review continues throughout the review process and the PMRA will make necessary label revisions to the proposed label provided by the applicant. Translation of label revisions resulting from the science evaluation will be provided by the PMRA. To facilitate timely issuance of the final label, bilingual draft labels must be submitted with the application.

The PMRA will communicate to the applicant any significant label changes resulting from the science evaluation before finalizing the product label. This will provide an opportunity for the applicant to clarify issues arising from the label revisions.

The label review process has changed a number of times since the 1996 version of the MOSP was published and it continues to evolve. The proposed changes in the revised MOSP include the following:

- 1) The requirement of bilingual draft labels at the time of application.
- 2) The label review being done in parallel with the science evaluation review.
- 3) The PMRA translating any changes identified during the review and providing the final label to the applicant at the same time as the final decision. (Note: the current 45-day label verification time for most submission categories/subtypes will be retained as part of the total review time).

### **4.2.3 Decision**

If there is sufficient scientific evidence to show that a product does not pose unacceptable health or environmental risks and that it has value, a decision to register the product will be made. The applicant will receive a registration decision letter indicating whether or not the product has been granted registration. At the same time, if applicable, the PMRA will issue the approved bilingual label and the certificate of registration.

As mentioned previously in Section 4.2.2 (Label Review), a proposed change under the revised MOSP is the issuance of an approved bilingual label, if applicable, at the time of registration decision.

### **4.3 Public Consultation**

A bilingual consultation document (Proposed Registration Decision) is published for all major decisions (for example, new active ingredients and major new uses of registered pesticides) as defined under subsection 28(1) *Pest Control Products Act*, unless the requirement to consult the public is explicitly exempted under paragraph 14(1)(b) of the Pest Control Products Regulations as a result of a conditional registration.

The consultation period for all Proposed Registration Decisions is 45 days from the date of publication. The comments received during the consultation period are considered before rendering the final regulatory decision.

This is not a change from current practice.

#### **4.3.1 Conditional Registration**

Applications for renewal of a conditional registration or for conversion to a full registration, upon the fulfilment of conditions specified in a section 12 notice, are treated as a Category B submission. Public consultation under subsection 28(1) of the *Pest Control Products Act* is required for all cases where consultation was postponed for a major decision under paragraph 14(1)(b) of the Pest Control Products Regulations.

This is not a change from current practice.

### **4.4 Renegotiation of Review Times**

Review times as proposed in Appendix II may need to be renegotiated by the PMRA and the applicant to either synchronize the reviews of related submissions or to allow for the review of additional information required to make a registration decision. For example, for submissions that involve the use of tiered data requirements (such as non-conventional pesticides and microbial pest control agents), more time will be required to review a subsequent tier of data.

While the renegotiation of review times is sometimes warranted (for example, joint review submissions with other jurisdictions), this approach will only be considered if circumstances warrant, and to replace and streamline the current process after a response is received to an evaluation deficiency, which includes 45 days for screening, 180 days for a second review and 45 days for making a decision.

#### **4.5 Performance Measures**

##### **Completeness Check Time**

The time taken from initial receipt of an application (or from when a response to a verification deficiency is received) to the end of the first screening.

The completeness check time would replace the separate reporting of verification time and screening time.

##### **Review Time**

The time after the completeness check is completed to when a final regulatory decision is made, excluding applicant time (when a submission is placed "on-hold" pending an applicant response to a Notice of Deficiencies) and excluding public consultation time.

The proposed changes to review include expanding the definition of review to include everything after the completeness check except the 45 day consultation period.

##### **Applicant Time**

The time when a submission is pending an applicant to respond to a Notice of Deficiencies, in other words, when the completeness check or review clocks are "on-hold".

While not specifically mentioned in PRO96-01, this performance measure has been used for a number of years. There is no proposed change in this performance measure.

##### **Total Time**

From the date that an application is received to the date that the submission is registered/rejected/withdrawn/denied/completed.

While not specifically mentioned in PRO96-01, this performance measure has been used for a number of years to measure the performance of the submission management process. It is a shared measure between applicants and the PMRA. There is no proposed change in this performance measure.

##### **Performance Standard**

Note: The PMRA's current performance standard is that 90% of submissions in all categories are to be processed within the applicable review timelines. Under the revised MOSP, it is proposed that this performance standard be changed to 85% (that is to say, 85% of submissions are to be processed within the applicable review timelines). This change will give PMRA more flexibility to reallocate resources to address stakeholder requests for expedited reviews of certain products (for example, Program 914).

## **4.6 Dispute Resolution**

To minimize disputes, applicants are encouraged to familiarize themselves with the pesticide registration process and registration requirements and to request, when appropriate, a presubmission consultation.

The PMRA will make every effort to manage and resolve disputes at the organizational level at which they take place.

Disputes regarding the screening of an application including screening deficiencies, data requirements, screening timeline and also requests by applicants for an extension of the timeline for responding to a Notice of Deficiencies, should be addressed to the screening officer assigned to the submission.

Disputes regarding the review of the submission, including Notices of Deficiencies, data requirements, review timeline, labelling revisions and review decision, should be addressed to the administrative coordinator assigned to the submission.

If mechanisms for early dispute resolution fail, applicants should contact the Chief Registrar's Office of the PMRA. For major regulatory decision proposals, there is an opportunity for the applicant (or any member of the public) to comment during the public consultation period. In addition, for any major regulatory decisions for which a public consultation under section 28(1) of the *Pest Control Products Act* was required before a registration decision was taken, the applicant (or any member of the public) has another opportunity to comment by filing a Notice of Objection requesting the reconsideration of the decision within 60 days after the decision is made public.

For additional information on the reconsideration of decision process, please consult the Pesticides and Pest Management portion of Health Canada's website (Request a Reconsideration of Decision) or contact the Health Canada PMRA's Pest Management Information Service.

This is a new addition to the MOSP.

## **5.0 Next Steps**

As previously stated, a summary of the differences between PRO96-01 and the proposed changes identified in this consultation document (Regulatory Proposal PRO2010-05, *Revised Management of Submissions Policy*) can be found in Appendix IV.

Following the consultation period of this document, the proposed revisions to the MOSP process will be finalized and implementation of the proposed amendments, if accepted, will be phased in as information management tools are developed to support the proposed changes to submission tracking and reporting. Before making a final decision, the PMRA will consider all comments received in response to this consultation document. The PMRA will accept written comments on this proposal up to 60 days from the date of publication of this document. Please forward all comments to PMRA Publications.

In the interim, the PMRA will continue to use the current process and also pilot projects to phase-in the proposed revisions. Finally, in an effort to seek further efficiencies, the PMRA will continue to refine the MOSP as required, in consultation with stakeholders.



## Appendix I Current MOSP Performance Timelines For Review of Pest Control Product Applications

(Current Performance Standard = 90% of submissions in all categories to be processed within the review time shown).

**Table 1 Category A Submission Performance Timelines in Number of Calendar Days (includes new active ingredients, import MRLs on new active ingredients and major new use registration)**

Category Subdivision	Verification (Level A)	Screening (Level B)	Review (Levels C-F)	Public Consultation (Level G)	Decision (Level H)	Verification of Final Label (Level I)
Conventional Chemical	7	45	550	45	45	45
Reduced-Risk*, Other Biopesticides, NSCLP**	7	45	450	45	45	45
Microbials	7	45	365	45	45	45
SCLP***	7	45	180	45	45	45
URMUR	7	45	365 or 180	45	45	45
Joint Reviews	30		Negotiated	45	45	45
Program 914	7	45	Negotiated (<365 days)	45	45	45
Import MRL****	7	45	550			45

\* Reduced risk refers to the expedited review timelines as outlined in Regulatory Directive DIR2002-02, *The PMRA Initiative for Reduced-Risk Pesticides*.

\*\* Non Straight Chain Lepidopteran Pheromone

\*\*\* Straight Chain Lepidopteran Pheromone

\*\*\*\* The reduced-risk timelines don't apply in this case

**Table 2 Category B Submission Performance Timelines in Number of Calendar Days (includes new formulations, changes in current formulations, new hosts and/or pests added to existing products, renewal or conversion of conditional registration, new source of currently registered active ingredient, emergency registrations and changes in rates and methods of application)**

Category Subdivision	Verification (Level A)	Screening (Level B)	Review (Levels C–F)	Public Consultation (Level G)	Decision (Level H)	Verification of Final Label (Level I)
Conventional Chemical	7	45	365	NA		45
Reduced-Risk*, Other Biopesticides, NSCLP**	7	45	300	NA		45
Renewal or Conversion of Conditional Registration ****	7	45	365	45	45	45
Microbials	7	45	180	NA		45
Pheromones – SCLP***	7	45	180	NA		45
New MRL for previously assessed active ****	7	45	365	NA		45
Emergency use (Priority) Reduced-Risk*, Other Biopesticides, NSCLP**	7	45	300	NA		45
Emergency use (Priority) Conventional Chemicals	7	45	365	NA		45
Emergency use (Priority) for microbials and SCLP***	7	45	180	NA		45

\* Reduced risk refers to the expedited review timelines as outlined in Regulatory Directive DIR2002-02, *The PMRA Initiative for Reduced-Risk Pesticides*.

\*\* Non Straight Chain Lepidopteran Pheromone

\*\*\* Straight Chain Lepidopteran Pheromone

\*\*\*\* The reduced-risk timelines don't apply in this case

**Table 3 Category C Submission Performance Timelines in Number of Calendar Days (includes changes to technical grade active ingredient, product chemistry, new or changed labels, similar products, master product registrations, administrative changes or re-instatements)**

Category Subdivision	Verification (Level A)	Screening (Level B)	Review (Levels C)	Verification of Final Label (Level I)
Standard	7	225 combined screen and review		45
		45	180	
Streamlined	7	45	98	45

**Table 4 Category D Submission and Pre-submission Performance Timelines in Number of Calendar Days**

Category Subdivision	Verification (Level A)	Screening (Level B)	Review (Levels C–E)	Verification of Final Label (Level I)
IMEP	7	14	32	45
OUI equivalency certificate	7	14	56	45
OUI permit	30 days total time			
GROU equivalency certificate	To be determined			
GROU permit	30 days total time			
URMULE pre-submission	97 days total time			
URMULE Conventional Chemical	247 days total time			
URMULE–Microbial, NSCLP*, SCLP**, Reduced-Risk***, Other Biopesticides	217 days total time			
URMULE Joint Review	Negotiated			
Master Copy	7	21		21
Private Label	7	10		n/a
Registration Renewal	March 15 <sup>th</sup> performance timeline			
Discontinuation	7	45		

\* Non Straight Chain Lepidopteran Pheromone

\*\* Straight Chain Lepidopteran Pheromone

\*\*\* Reduced risk refers to the expedited review timelines as outlined in Regulatory Directive DIR2002-02, *The PMRA Initiative for Reduced-Risk Pesticides*.

**Table 5 Category E Submission Performance Timelines in Number of Calendar Days  
(Research Permits and Research Notifications)**

<b>Category Subdivision</b>	<b>Verification (Level A)</b>	<b>Screening (Level B)</b>	<b>Review (Levels C-E)</b>	<b>Verification of Final Label (Level I)</b>
New Active (Food and Non Food Use)	7	14	152	7
New Use	7	14	62	7
Notification of Research	23			7

## Appendix II Proposed Revisions to MOSP Performance Timelines for Pest Control Product Applications

(Proposed Performance Standard = 85% of submissions to be processed within the applicable review timelines)

**Table 1 Category A Submission Performance Timelines in Number of Calendar Days (includes new active ingredients, new MRLs and major new use registration)**

Category Subdivision	Completeness Check in Days	Review Time in Days (Months)*	Public Consultation in Days
Conventional Chemical	37	655 (22)	45
Reduced-Risk**, Other Biopesticides, NSCLP***	37	555 (18.5)	45
Microbials	37	470 (15.5)	45
Pheromones-SCLP****	37	285 (9.5)	45
Joint Reviews	37	negotiated	45
URMUR	37	470 (15.5)	45
URMUR-SCLP****	37	285 (9.5)	45
Program 914	37	negotiated (<470 days)	45
Import MRL*****	37	655 (22)	n/a

\* Review Time = the time after the end of the completeness check to the final regulatory decision. The review time excludes:

- a 45-day public consultation period if applicable
- time when a submission is "on-hold" pending the applicant
- additional time that may be required by the PMRA to examine additional information submitted by the applicant in response to a Notice of Deficiencies

\*\* Reduced risk refers to the expedited review timelines as outlined in Regulatory Directive DIR2002-02, *The PMRA Initiative for Reduced-Risk Pesticides*.

\*\*\* Non Straight Chain Lepidopteran Pheromone

\*\*\*\* Straight Chain Lepidopteran Pheromone

\*\*\*\*\* The reduced-risk timelines don't apply in this case

**Table 2 Category B Submission Performance Timelines in Number of Calendar Days (includes new formulations, changes in current formulations, new hosts and/or pests added to existing products, renewal or conversion of conditional registration, new source of currently registered active ingredient, emergency registrations and changes in rates and methods of application)**

Category Subdivision	Completeness Check	Review Time in days (months)*	Public Consultation in Days
Conventional Chemical	37	425 (14)	n/a
Streamlined (application rate changes, tank mixes, new pests or changes to level of control)	37	158 (5)	n/a
Reduced-Risk**, Other Biopesticides, NSCLP***	37	360 (12)	n/a
Renewal or Conversion of Conditional Registration (with public consultation)****	37	470 (15.5)	45
Renewal or Conversion of Conditional Registration (without public consultation)****	37	425 (14)	n/a
Microbials	37	240 (8)	n/a
Pheromones – SCLP****	37	240 (8)	n/a
New MRL for previously assessed active ingredient*****	37	425 (14)	n/a
Emergency use (Priority): Reduced-Risk**, Other Biopesticides, NSCLP***	37	<360 (12)	n/a
Emergency use (Priority): Conventional Chemicals	37	<425 (14)	n/a
Joint Review	37	negotiated	n/a

\* Review Time = the time after the end of the completeness check to the final regulatory decision. The review time excludes:

- a 45-day public consultation period if applicable
- time when a submission is "on-hold" pending the applicant
- additional time that may be required by the PMRA to examine additional information submitted by the applicant in response to a Notice of Deficiencies

\*\* Reduced risk refers to the expedited review timelines as outlined in Regulatory Directive DIR2002-02, *The PMRA Initiative for Reduced-Risk Pesticides*.

\*\*\* Non Straight Chain Lepidopteran Pheromone

\*\*\*\* Straight Chain Lepidopteran Pheromone

\*\*\*\*\* The reduced-risk timelines don't apply in this case

**Table 3 Category C Submission Performance Timelines in Number of Calendar Days (includes changes to technical grade active ingredient, product chemistry, new or changed labels, similar products, master product registrations, administrative changes or re-instatements)**

Category Subdivision	Completeness Check Time in Days	Review Time in Days (months)
Standard	37	240 (8)

**Table 4 Category D Submission and Presubmission Performance Timelines in Number of Calendar Days**

Category Subdivision	Completeness Check Time in Days	Review Time in Days
IMEP	21	46
OUI equivalency certificate	21	70
OUI permit	30 days total time	
GROU equivalency certificate	To be determined	To be determined
GROU permit	30 days total time	
URMULE presubmission	97 days total time	
URMULE Standard Chemical	247 days total time	
URMULE – Microbial, SCLP*, NSCLP**, Reduced-Risk***, Other Biopesticides	217 days total time	
URMULE Joint Review	negotiated	
Master Copy	7 verification	42 screen and review
Private Label	7 verification	10 screen and review
Registration Renewal	Complete by March 15th	
Discontinuation	7 verification	45 screen and review

\* Straight Chain Lepidopteran Pheromone

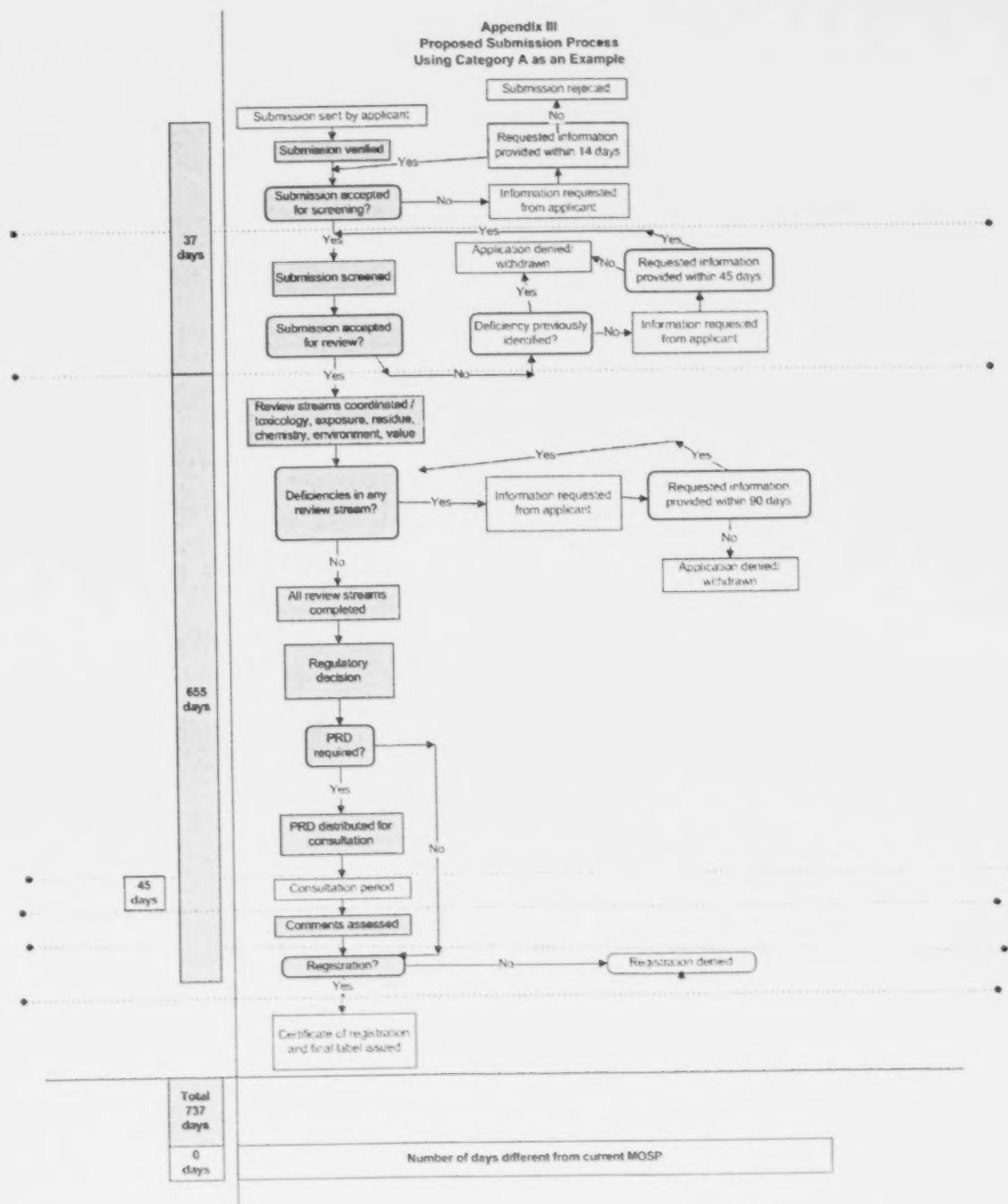
\*\* Non Straight Chain Lepidopteran Pheromone

\*\*\* Reduced risk refers to the expedited review timelines as outlined in Regulatory Directive DIR2002-02, *The PMRA Initiative for Reduced-Risk Pesticides*.**Table 5 Category E Submission Performance Timelines in Number of Calendar Days (for Research Permits and Research Notification)**

Category Subdivision	Completeness Check Time in Days	Review Time in Days
New technical grade active ingredient (Food and Non-Food Use)	21	159
New Use	21	69
Notification of Research	30 days total	



# Appendix III Proposed Submission Process Using Category A as an Example





**Appendix IV Summary of the Differences Between PRO96-01,  
Management of Submissions Policy, and PRO2010-05,  
Revised Management of Submissions Policy**

		<b>PRO96-01 MOSP</b>	<b>PRO2010-05 Revised MOSP Proposal</b>	<b>Expected Impact</b>
Performance Measures	Verification Screening	Separate reporting of verification and screening	Report combined completeness check on most submission categories. Verification considered started once a complete application has been received.	Any time gained early on during verification can be applied to screening.
	Review	From completion of screening until a proposed regulatory decision.	For most submission categories and subtypes, redefine review to include all PMRA time until a regulatory decision. (For joint reviews the definition of review would not change).	More harmonized approach with other jurisdictions (USEPA, Australia).
Timelines	Screening	45 days for standard submissions	30 days for standard submissions	15 days taken from screening and added to review time.
	Labeling	45 days for standard submissions	Done in parallel with review	45 days from previous labeling stage added to review time.
"On-hold"	Verification	Deficient submissions rejected	Addition of verification "on-hold" option to resolve deficient submissions.	Reduces need to reject incomplete applications. Performance measures begin once a complete package is received.
	Fees	Separate Pending Fees "on-hold" for full 45 day period	Review clock will start or restart as soon as fees are paid	Will reduce pending fee "on-hold" time.
	Screening	Starts over after "on-hold"	Reduced to 15 days for second screening.	Reduces up to 30 days following every "on-hold".
	Review	Full review timeline starts over when response received to deficiency	Timelines will continue from when placed "on-hold"	Eliminates long loops caused by "on-holds".

		<b>PRO96-01 MOSP</b>	<b>PRO2010-05 Revised MOSP Proposal</b>	<b>Expected Impact</b>
"On-hold" (cont'd)	Review (cont'd)	Submission screened following preliminary review deficiency and evaluation deficiency	No additional screening once a submission is in the review stage	45-day reduction after every review "on-hold".
		Second 180 day review following an evaluation deficiency	No second review. However, timelines may be renegotiated to allow for review of any new data required to make a registration decision.	180-day reduction after every review "on-hold". Review timeline will continue rather than starting over again but may need to be renegotiated
		All review streams must identify deficiencies before issuing a consolidated Notice of Deficiencies	Separate Notice of Deficiencies for specific data parts may be issued.	Eliminates waiting for all review streams to have identified deficiencies before issuing notice to applicant.
				Applicant may receive multiple deficiency notices for one application.
Labeling		PMRA requests applicant to make edits and translation after review.	The PMRA will translate review amendments and provide final labels to applicant.	Eliminates version control problems and issues that may arise after review, including delays caused by translations.
			Bilingual draft labels required upfront	
			Label review will be done in parallel with the science review.	Bilingual labels required on application. 45 days of label review can be applied to review time. The PMRA will communicate label changes to applicants during the science review process.
Categories	Name Change	Streamlined Category C	Change to Streamlined Category B	More reflective of Category B submission type.